

1651



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vincent Fischetti et al.

Appl. No.: 10/067,979

Group Art Unit: 1651

Filing Date: February 8, 2002

Examiner: Prats, Francisco Chandler

Title: Therapeutic Treatment of Upper Respiratory Infections

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97**

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Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents is being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action that would be appropriate to antedate or otherwise remove as a competent reference any document that is determined to be a *prima facie* prior art reference against the claims of the present application.

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

U.S. Serial No.: 10/067,979

In re Vincent Fischetti et al.

Attached as Appendix A is a list of all patents and applications filed by the present inventive entity relating to phage associated lytic enzymes and their uses. The listed U.S. patents are cited in the attached form SB/08A.

Attached herewith as Appendices 1-6 are copies of International Search Reports received in PCT applications corresponding to applications listed in Appendix A. For the Examiner's convenience, the cover sheet and claims for each of the PCT applications are also provided.

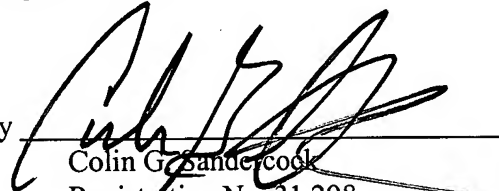
Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

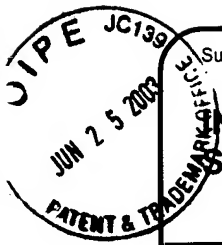
Respectfully submitted,

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 11

Complete if Known

Application Number	10/067,979
Filing Date	2/8/02
First Named Inventor	Vincent Fischetti
Group Art Unit	1651
Examiner Name	PRATS, FRANCISCO CHANDLER
Attorney Docket Number	

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US- 6056954	05/02/00	Fischetti, et al.	
	2	US- 5997862	12/07/99	Fischetti, et al.	
	3	US- 5985271	11/16/99	Fischetti, et al.	
	4	US- 5688501	11/18/97	Merril, et al.	
	5	US- 4742981	05/10/88	Converse	
	6	US- 2019789	11/05/35	Mahannah	
	7	US- 2763931	09/25/56	McMillan	
	8	US- 5479732	01/02/96	Burtch, et al.	
	9	US- 3465445	09/09/69	Fisher	
	10	US- 2315260	03/30/43	Lancaster	
	11	US- 5604109	02/18/97	Fischetti, et al.	
	12	US- 5260292	11/09/93	Robinson, et al.	
	13	US- 4957686	09/18/90	Norris	
	14	US- 6017528	01/25/00	Fischetti, et al.	
	15	US- 6132970	10/17/00	Stemmer	
	16	US- 3852424	12/03/74	Gaeumann, et al.	
	17	US- 6264945	07/24/01	Fischetti, et al.	
	18	US- 6254866	07/03/01	Fischetti, et al.	
	19	US- 6248324	06/19/01	Fischetti, et al.	
	20	US- 6238661	05/29/01	Fischetti, et al.	

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**FOREIGN PATENT DOCUMENTS**

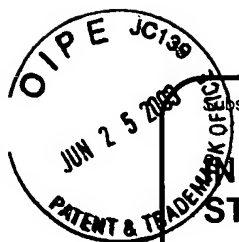
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	21	EP-0510907 A 2	10/28/92	Agricultural & Food Res.		
	22	WO-9702351	01/23/97	CIBA Geigy AG, et al.		
	23	WO-9607329	03/14/96	Univ. Maryland		
	24	WO-9904809	02/04/99	Ambi, Inc.		
	25	FR-2357246	02/03/78	Martinez		
	26	WO-9531562	11/23/95	Quest International B.V.		
	27	EP-587541 A1	03/16/94	Tecnogen ScpA		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



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Sheet 2 of 11

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	28	US- 6056955	05/02/00	Fischetti, et al.	
	29	US- 5882631	03/16/99	Suga, et al.	
	30	US- 5741487	04/21/98	Asai, et al.	
	31	US- 6113887	09/05/00	Mori, et al.	
	32	US- 4122158	10/24/78	Schmitt	
	33	US- 3983209	09/28/76	Schmitt	
	34	US- 4885163	12/05/89	Shaar, et al.	
	35	US- 6177554	01/23/01	Woo, et al.	
	36	US- 6187757	02/13/01	Clackson, et al.	
	37	US- 5162226	11/10/92	Beachey, et al.	
	38	US- 6335012	01/01/02	Fischetti, et al.	
	39	US- 6326002	12/04/01	Fischetti, et al.	
	40	US- 6277399	08/21/01	Fischetti, et al.	
	41	US- 4062941	12/13/77	Davies	
	42	US- 5571667	11/05/96	Chu, et al.	
	43	US- 5514602	05/07/96	Brooks Jr, et al.	
	44	US- 5500350	03/19/96	Baker, et al.	
	45	US- 5384265	01/24/95	Kidwell, et al.	
	46	US- 4361537	11/30/82	Deutsch, et al.	
	47	US- 5120643	06/09/92	Ching, et al.	

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	48	WO-9323544	11/25/93	The University Court of the University of Glasgow		
	49	EP-0293249 A1	11/30/88	Amrad Corporation Limited		
	50	EP-0646646 A2	04/05/95	Bristol-Myers Squibb Company		
	51	EP-0359873 A1	03/28/90	The Public Health Research Inst. of the City of New York		

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Sheet	3	of	11
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		Number - Kind Code <sup>2</sup> (if known)			
	52	US-4948726	08/14/90	Longoria	
	53	US- 4459361	07/10/84	Geffer	
	54	US- 4552839	11/12/85	Gould, et al.	
	55	US- 4313734	02/02/82	Leuversing	
	56	US- 4847199	07/11/89	Snyder, et al.	
	57	US- 4497900	02/05/85	Abram, et al.	
	58	US- 4707543	11/17/87	Zollinger, et al.	
	59	US- 5763251	06/09/98	Gasson	
	60	US- 6159688	12/12/00	Borchert, et al.	
	61	US- 4784948	11/15/88	Scott, et al.	
	62	US- 5760026	06/02/98	Blackburn, et al.	
	63	US- 5602040	02/11/97	May, et al.	
	64	US- 4521252	06/04/85	Miyake, et al.	
	65	US- 4355022	10/19/82	Rabussay	
	66	US- 4115546	09/19/78	Vidra, et al.	
	67	US- 4116327	09/26/78	Eglinton, et al.	
	68	US- 3929994	12/30/75	Hirsch, et al.	
	69	US- 6083684	07/04/00	Gasson	
	70	US- 5360617	11/01/94	Gasson	
	71	US- 5079174	01/07/92	Buck, et al.	

## FOREIGN PATENT DOCUMENTS

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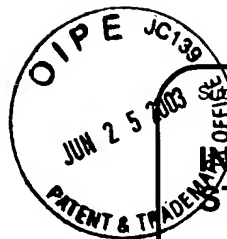
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Sheet 5 of 11

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First Named Inventor	Vincent Fischetti
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Examiner Name	PRATS, FRANCISCO CHANDLER
Attorney Docket Number	

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## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	82	KH Nasibulini et al; RU-2103991; Composition for treating streptococcal diseases - comprises purified concentrate of streptococcal bacteriophage, solution of quinosol, dry lanolin, albumin and vegetable oil; XP-002141110	
	83	LD Demidova et al; RU2064299; Cattle mastitis therapeutic preparation - comprises lyso: amidase of specific lytic activity and mono- and di-basic sodium phosphate(s); XP-002141111	

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Sheet 6 of 11

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	84	BABENKO et al. Enzymatic lysis of staphylococci in relation to their species and strain properties, 1990, Database Medline Online, US National Library of Medicine, Bethesda, MD, US, Database Accession No. 90297672 XP002170795, abstract only	
	85	BARTELL, et al., Origin of polysaccharide depolymerase associated with bacteriophage infection, Journal of Virology, March 1969, pp. 290-296, Vol. 3, No. 3	
	86	BEHNKE, et al., Cloning and expression in Escherichia coli, Bacillus subtilis and Streptococcus sanguis of a gene for staphylokinase - a bacterial plasminogen activator, Mol Gen Genet, December 1987, pp. 528-534, Vol. 210	
	87	BESSEN, et al., Chemical characterization of binding properties of opacity-associated protein II from Neisseria gonorrhoeae, Infection and Immunity, January 1987, pp. 141-147, Vol. 55, No. 1	
	88	BIZIULEVICHUS, et al., In vivo studies on lysosubtilin: 3. Efficacy for treatment of mastitis and superficial lesions of the udder and teats in cows, 1998, Database Biosis Online, Biosciences Information Service, Philadelphia, PA, US, Database Accession No. PREV199800492606, XP002183274, abstract only	
	89	BOIZET, et al., Cloning, expression and sequence analysis of an endolysin-encoding gene of Lactobacillus bulgaricus bacteriophage mv1, Gene, 2000, pp. 61-67, Vol. 94	
	90	CALDWELL, et al., Purification and partial characterization of the major outer membrane protein of Chlamydia trachomatis, Infection and Immunity, March 1981, pp. 1161-1176, Vol. 31, No. 3	
	91	YOUNG et al. Phages will out: strategies of host cell lysis, Trends in Microbiology, Volume 8 No. 3, March 2000, pp 120-127	
	92	CORBEL, et al., Soluble antigens obtained from influenza virus by treatment with non-ionic detergent, J Hyg., Camb., 1970, pp. 81-96, Vol. 68	
	93	CROUX, et al., Interchange of functional domains switches enzymes specificity: construction of a chimeric pneumococcal-clostridial cell wall lytic enzyme, Molecular Microbiology, 1993, pp.1019-25, Vol. 9, No. 5	
	94	DIAZ, et al., Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes, Proc. Natl. Acad. Sci. USA, October 1990, pp. 8125-8129, Vol. 87	

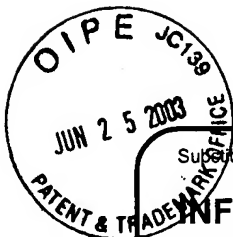
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C m p l t i f K n o w n

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	95	DIAZ, et al., Chimeric pneumococcal cell wall lytic enzymes reveal important physiological and evolutionary traits, Journal of Biological Chemistry, March 25, 1991, pp. 5464-5471, Vol. 266, No. 9	
	96	DIXON, et al., Lysostaphin: an enzymatic approach to staphylococcal disease. III. Combined lysostaphin-methicillin therapy of established staphylococcal abscesses in mice, The Yale Journal of Biology and Medicine, August 1968, pp. 62-68, Vol. 41, No. 1	
	97	FISCHETTI, et al., Size variation of the M protein in group A streptococci, Journal of Exp. Med., June 1, 1985, pp. 1384-1401, Vol. 161, No. 6	
	98	GARCIA, et al., Bacteriophages of Streptococcus pneumoniae: A molecular approach, Microbial Drug Resistance, Summer 1997, pp. 165-176, Vol. 3, No. 2	
	99	GARCIA, et al., Cloning, purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysin, Journal of Virology, August 1987, pp. 2573-2580, Vol. 61, No. 8	
	100	GARCIA, et al., Modular organization of the lytic enzymes of streptococcus pneumoniae and its bacteriophages, Gene, 1990, pp. 81-88, Vol. 86	
	101	GERARDY-SCHANN, et al., Molecular cloning and functional expression of bacteriophage PK1E-encoded endoneuraminidase Endo NE, Molecular Microbiology, May 1995, pp. 441-450, Vol. 16, No. 3	
	102	GOLDBERG, et al., Studies in experimental staphylococcal endocarditis in dogs, Antimicrobial Agents and Chemotherapy, 1967, pp. 45-53	
	103	HARRISON, et al., Lysostaphin in experimental renal infections, Journal of Bacteriology, February 1967, pp. 520-524, Vol. 93, No. 2	
	104	HARRISON, et al., Therapeutic activity of lysostaphin in experimental staphylococcal infections, Canadian Journal of Microbiology, January 1967, pp. 93-97, Vol. 13, No. 1	
	105	HAYASHI, et al., Effects of N-Acetylmuramidase from Streptomyces rutgersensis H-46 as a food preservative, Agric. Biol. Chem., December 1989, pp. 3173-3177, Vol. 53, No. 12	

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	106	HAYASHIDA, et al., Further characterization of PL-1 phage associated N-acetylmuramidase of Lactobacillus casei, Journal of General Microbiology, May 1987, pp. 1343-1349, Vol. 133, No. 5	
	107	HIGUCHI, et al., Transfection of streptococcus sanguis by phage deoxyribonucleic acid isolated from streptococcus mutans, Infection and Immunity, March 1977, pp. 945-949, Vol. 15, part 3	
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Sheet 9 of 11

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Application Number	10/067,979
Filing Date	2/8/02
First Named Inventor	Vincent Fischetti
Group Art Unit	1651
Examiner Name	PRATS, FRANCISCO CHANDLER
Attorney Docket Number	

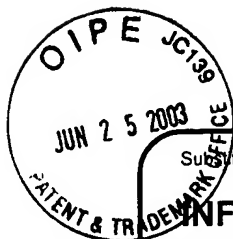
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Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
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Sheet 10 of 11

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First Named Inventor	Vincent Fischetti
Group Art Unit	1651
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Attorney Docket Number	

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Sheet	11	of	11
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Attorney Docket Number	

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Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	133	US-5605793	02/25/97	Stemmer	
	134	US- 6355477	03/12/02	Fischetti et al	
	135	US- 6331405	12/18/01	Rambukkana et al	
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# Appendix A

Serial No.	Filing Date	Patent N .	Issue Date
07/621,716	June 18, 1984	4,784,948	November 15, 1988
09/257,025	February 25, 1999	6,017,528	January 25, 2000
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09/703,656	November 2, 2000		
09/703,685	November 2, 2000		

## Appendix A

<b>Serial No.</b>	<b>Filing Date</b>	<b>Patent N .</b>	<b>Issue Dat</b>
09/703,686	November 2, 2000		
09/703,739	November 2, 2000		
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Serial No.	Filing Date	Patent No.	Issue Date
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10/252,031	September 23, 2002		
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